



DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Parts 60 and 65

[Document No. AMS-LS-13-0004]

RIN 0581-AD29

Mandatory Country of Origin Labeling of Beef, Pork, Lamb, Chicken, Goat Meat, Wild and Farm-raised Fish and Shellfish, Perishable Agricultural Commodities, Peanuts, Pecans, Ginseng, and Macadamia Nuts

AGENCY: Agricultural Marketing Service (AMS), USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the Country of Origin Labeling (COOL) regulations to change the labeling provisions for muscle cut covered commodities to provide consumers with more specific information, and amend the definition for "retailer" to include any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act (PACA). The COOL regulations are issued pursuant to the Agricultural Marketing Act of 1996. The Agency is issuing this rule to propose changes to the labeling provisions for muscle cut covered commodities to provide consumers with more specific information and is proposing other modifications to enhance the overall operation of the program.

DATES: Comments must be submitted on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER.]

ADDRESSES: Interested persons may submit written comments on this proposed rule using the following address:

Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. *Instructions:* All submissions received must include the docket number AMS-LS-13-0004; and/or Regulatory Information Number (RIN) 0581-AD29 for this rulemaking. Comments may also be submitted to Julie Henderson, Director, COOL Division, Livestock, Poultry, and Seed Program, Agricultural Marketing Service, U.S. Department of Agriculture (USDA); STOP 0216; 1400 Independence Avenue S.W., Room 2620-S; Washington, DC 20250-0216. All comments should reference docket number AMS-LS-13-0004 and note the date and page number of this issue of the **Federal Register**.

Submitted comments will be available for public inspection at <http://www.regulations.gov> or at the above address during regular business hours. Comments submitted in response to this proposed rule will be included in the records and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the Internet at the above address.

FOR FURTHER INFORMATION CONTACT: Erin Morris, Deputy Associate Administrator, AMS, USDA, by telephone on 202/690-4024, or via e-mail at: erin.morris@ams.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Farm Security and Rural Investment Act of 2002 (2002 Farm Bill) (Pub. L. 107-171), the 2002 Supplemental Appropriations Act (2002 Appropriations) (Pub. L. 107-206), and the Food, Conservation and Energy Act of 2008 (2008 Farm Bill) (Pub. L. 110-234) amended the Agricultural Marketing Act of 1946 (Act) (7 U.S.C. 1621 et seq.) to require retailers to notify their customers of the country of origin of covered commodities. Covered commodities include muscle cuts of beef (including veal), lamb, chicken, goat, and pork; ground beef, ground lamb, ground chicken, ground goat, and ground pork; wild and farm-raised fish and shellfish; perishable agricultural commodities; macadamia nuts; pecans; ginseng; and peanuts. AMS published a final rule for all covered commodities on January 15, 2009 (74 FR 2658), which took effect on March 16, 2009.

Executive Summary

Purpose of the Regulatory Action

In June 2012, in a WTO case brought by Mexico and Canada, the WTO Appellate Body (AB) affirmed a previous WTO Panel's finding that the COOL requirements for muscle cut meat

commodities were inconsistent with U.S. obligations under the WTO Agreement on Technical Barriers to Trade (TBT Agreement). In particular, the AB affirmed the Panel's determination that the COOL requirements were inconsistent with the TBT Agreement's national treatment obligation to accord imported products treatment no less favorable than that accorded to domestic products. The WTO Dispute Settlement Body adopted its recommendations and rulings on July 23, 2012. The United States has until May 23, 2013, to comply with the WTO ruling.

As a result of this action, the Agency reviewed the overall regulatory program and is issuing this rule, under the authority of the Agricultural Marketing Act (7 U.S.C. 1621 et seq.), to propose changes to the labeling provisions for muscle cut covered commodities and other modifications to improve the overall operation of the program. The Agency expects that these changes will improve the overall operation of the program and also bring the current mandatory COOL requirements into compliance with U.S. international trade obligations.

Summary of the Major Provisions of the Regulatory Action in Question

Under this proposed rule, origin designations for muscle cut covered commodities derived from animals slaughtered in the United States would be required to specify the production steps of birth, raising, and slaughter of the animal from which the

meat is derived that took place in each country listed on the origin designation. In addition, this proposed rule would eliminate the allowance for any commingling of muscle cut covered commodities of different origins. These changes will provide consumers with more specific information about muscle cut covered commodities.

Costs and Benefits

The major cost of implementing the proposed amendments will be incurred at the packing or processing facility, in the case of pre-labeled products, or at the retail level, in the case of products labeled at retail. The estimated number of firms that would need to augment labels for muscle cut covered commodities is 2,808 livestock processing and slaughtering firms, 38 chicken processing firms, and 4,335 retailers. This totals 7,181 firms that would need to augment the mandatory COOL information presented on labels for muscle cut covered commodities.

Based on 2009 data, the Food Safety and Inspection Service (FSIS) estimated there were approximately 121,350 raw meat and poultry unique labels submitted by official establishments (i.e., establishments regulated by FSIS) and approved by the Agency (76 FR 44862). Assuming the upper bound estimate of 121,350 unique labels, the Agency preliminarily estimates the midpoint cost of the proposed rule for this label change is \$32,764,500 with a range of \$16,989,000 to \$47,326,500.

The Agency believes that the incremental economic benefits from the proposed labeling of production steps will be comparatively small relative to those that were discussed in the 2009 final rule.

A complete discussion of the cost and benefits can be found under the Executive Order 12866 section.

Summary of Proposed Changes to the COOL Regulations

Definitions

In the regulatory text for fish and shellfish (7 CFR part 60) and for all other covered commodities (7 CFR part 65), the definition for "retailer" is proposed to be amended to include any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act (PACA) of 1930 (7 U.S.C. 499a(b)). This change would more closely align with the language contained in the PACA regulation and would help clarify that all retailers that meet the PACA definition of a retailer, whether or not they actually have a PACA license, are also covered by COOL.

Proposed Changes to the Labeling Provisions for Muscle Cut Covered Commodities

As a result of the Agency's review of the program regulations, the Agency is proposing to require that all origin designations for muscle cut covered commodities slaughtered in the United States specify the production steps of birth,

raising, and slaughter of the animal from which the meat is derived that took place in each country listed on the origin designation. The requirement to include this information will apply equally to all muscle cut covered commodities derived from animals slaughtered in the United States. This requirement will provide consumers with more specific information on which to base their purchasing decisions without imposing additional recordkeeping requirements on industry. The Agency considers that these changes, which are discussed in detail below, are consistent with the provisions of the statute.

Labeling Covered Commodities of United States Origin

Under the current COOL regulations, for muscle cut covered commodities derived from animals that were born, raised, and slaughtered in the United States, the origin is allowed to be designated as "Product of the U.S."

Under this proposed rule, the United States country of origin designation for muscle cut covered commodities would be required to include location information for each of the production steps (i.e., "Born, Raised, and Slaughtered in the United States").

Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin (from Animals Slaughtered in the United States)

For muscle cut covered commodities of multiple countries of origin that include the United States, the current COOL regulations recognize two basic scenarios.

The first scenario deals with meat derived from animals that were born in another country (and thereby raised for a period of time) and were imported as feeder cattle that were further raised and slaughtered in the United States. For these products, current COOL regulations allow the origin to be designated as "Product of the U.S. and Country X." Under this proposed rule, as with U.S.-only origin products, the origin designation for these products would be required to include location information for each of the production steps.

However, as discussed in the preamble of the January 15, 2009, final rule (74 FR 2658), if animals are raised in another country and the United States, the raising that occurs in the United States may take precedence over the minimal raising that occurred in the animal's country of birth. Accordingly, under this proposed rule, the production step related to any raising occurring outside the United States may be omitted from the origin designation of these products (e.g., "Born in Country X, Raised and Slaughtered in the United States" in lieu of "Born and Raised in Country X, Raised and Slaughtered in the United States").

This omission is not permitted in the relatively rare situation where an animal was born in the United States, raised in another country (or countries) and then raised and slaughtered in the United States, which would result in the muscle cut covered commodity being designated as having a solely U.S. country of origin.

The second scenario relates to muscle cut covered commodities derived from animals that were imported for immediate slaughter as defined in §65.180. In this scenario, under the current COOL regulations, these products are required to be designated as "Product of Country X and the United States."

Under this proposed rule, the origin designation for meat derived from animals imported for immediate slaughter would be required to include information as to the production steps taking place in the countries listed on the origin designation. However, the country of raising for animals imported for immediate slaughter as defined in §65.180 shall be designated as the country from which they were imported (e.g., "Born and Raised in Country X, Slaughtered in the United States").

Commingling

The current COOL regulations allow for commingling of different origins. For example, under the current COOL regulations, for muscle cut covered commodities derived from

animals born, raised, and slaughtered in the United States that are commingled during a production day with muscle cut covered commodities derived from animals that were raised and slaughtered in the United States, and are not derived from animals imported for immediate slaughter as defined in §65.180, the origin is allowed to be designated, for example, as Product of the United States, Country X, and (as applicable) Country Y. Similarly, under the current COOL regulations, for muscle cut covered commodities derived from animals that are born in Country X or Country Y, raised and slaughtered in the United States, that were commingled during a production day with muscle cut covered commodities that were derived from animals that are imported into the United States for immediate slaughter as defined in §65.180, the origin is allowed to be designated as Product of the United States, Country X, and (as applicable) Country Y.

This proposed rule would eliminate the allowance for any commingling of muscle cut covered commodities of different origins. As discussed above, all origin designations would be required to include specific information as to the place of birth, raising, and slaughter of the animal from which the meat is derived. Removing the commingling allowance allows consumers to benefit from more specific labels.

Labeling Imported Muscle Cut Covered Commodities

Under the current COOL regulations, imported muscle cut covered commodities retain their origin as declared to the U.S. Customs and Border Protection at the time the products entered the United States (i.e., Product of Country X) through retail sale.

Under this proposed rule, these labeling requirements for imported muscle cut covered commodities remain unchanged, although the Agency has restructured the regulatory text of this provision for clarity. As is permitted under the current COOL regulations, the Agency will continue to allow the origin designation to include more specific information related to production steps, provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

Executive Order 13175

This rule has been reviewed in accordance with the requirements of Executive Order 13175, Consultation and Coordination with Indian Tribal Governments. The review reveals that this regulation will not have substantial and direct effects on Tribal governments and will not have significant Tribal implications.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives,

and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been designated as a "significant regulatory action" under section 3(f) of Executive Order 12866, and, therefore, has been reviewed by the Office of Management and Budget (OMB). The Agency seeks comments and data on the estimated impacts of this rulemaking that may affect its designation under Executive Order 12866 and the Congressional Review Act.

Regulations must be designed in the most cost-effective manner possible to obtain the regulatory objective while imposing the least burden on society. This proposed rule would amend the COOL regulations (1) to change the labeling provisions for muscle cut covered commodities to provide consumers with more specific information and (2) to amend the definition for "retailer" to include any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act (PACA) to enhance the overall operation of the program.

Initial Analysis of Benefits and Costs

The baseline for this analysis is the present state of the beef, chicken, goat, lamb and pork industries, which have been subject to the requirements of mandatory COOL (7 CFR parts 60 and 65) since the effective date of the final rule on March 16, 2009. Under this proposed rule, COOL requirements would remain essentially unchanged for imported muscle cut covered commodities. However, labeling requirements would change for muscle cut covered commodities derived from animals slaughtered in the United States—whether exclusively of United States origin, of multiple countries of origin that include the United States, or imported for immediate slaughter in the United States. For those products, covered retailers would need to inform their consumers of the country in which the relevant production steps—born, raised, and slaughtered—occurred.

As mentioned above in the summary of proposed changes to the COOL regulations, the definition for “retailer” would be amended to more closely align with the language contained in the PACA regulation and help clarify that all retailers that meet the PACA definition of a retailer, whether or not they actually have a PACA license, are covered by COOL. The Agency believes that this change in definition will not substantially alter the number of retailers subject to the COOL regulations. Therefore, the analysis of benefits and cost from this proposed rule focuses solely on the potential effects of the proposed

amendments to the labeling provisions of the current COOL regulations.

Benefits: In the time since the Agency conducted the previous COOL regulation's Preliminary Economic Impact Analysis (PRIA) in 2003 (68 FR 61952) and the Final Regulatory Impact Analysis (FRIA) in 2009 (74 FR 2682), a number of studies have been published regarding the economic effects of mandatory COOL. However, the available literature has not addressed the potential benefits and costs of providing more specific information on production steps as proposed herein. As observed in the PRIA and the FRIA, the expected benefits from implementing mandatory COOL requirements remain difficult to quantify. This conclusion holds true for the proposed amendments to the labeling requirements under the current COOL regulations. The Agency invites comment on the benefits of this proposed rule and welcomes data that would help to inform a more quantifiable analysis.

Numerous comments received on previous COOL rulemaking actions indicate that there is interest by some consumers in the designation of the countries of birth, raising and slaughter on meat product labels. Specifying the production step occurring in each country listed on meat labels as proposed in this rule could provide additional benefits by providing more specific

information on which consumers can base their purchasing decisions.

In addition, this proposed rule would eliminate the allowance for commingling of muscle cut covered commodities of different origins. As discussed in the preamble, removing the commingling allowance will allow the labels proposed under this rule to provide specific information as to the place of birth, raising, and slaughter of the animal from which the meat is derived.

The Agency has been unable to quantify incremental economic benefits from the proposed labeling of production steps and therefore requests detailed comment and data on this issue, most notably detailed data or studies on the value to consumers of having COOL information. The Agency concluded in the PRIA and FRIA that the economic benefits from the COOL requirements are positive, but difficult to quantify. The Agency believes that incremental economic benefits from the proposed labeling of production steps are difficult to quantify, and will be comparatively small relative to those that were discussed in the 2009 final rule.

Costs: Two conditions are necessary to inform retail consumers of the location in which production steps occurred. First, the relevant information must be collected by packers from producers and then passed to retailers. Second, the

information must be made available by retailers to consumers through a placard, sign, label, sticker, or other format. Because of the steps that have been taken to achieve compliance with existing mandatory COOL requirements, the first condition has been met. That is, we do not anticipate that this proposed rule will require additional recordkeeping or any new systems to transfer information from one level of the production and marketing channel to the next. The Agency is seeking comment on these assumptions and welcomes data that would help to inform a more refined analysis of the impacts of the rule at various points in production. The information provided to consumers at retail would be augmented to include information on the location(s) in which the three major phases of production occurred. Thus some incremental costs of implementing the proposed amendments would result from modifying the label (or other format) to reflect the additional production step information. We are specifically asking for comment and data regarding the extent to which there may be additional costs to collect and transmit data along the production and marketing chain, and how current production, distribution, and retail merchandising practices may be affected by the proposed rule.

As previously mentioned, no changes are being proposed to the existing country of origin labeling of imported muscle cuts derived from animals slaughtered in another country. Those

products would continue to retain their origin as declared to the U.S. Customs and Border Protection at the time the products entered the United States through retail sale. Thus, there are no incremental costs associated with that scenario.

However, in the situation in which the covered muscle cut commodities are derived from animals slaughtered in the United States, labeling of the location(s) in which the animal was born, raised, and slaughtered would now be required. Packers and processors that provide muscle cut covered commodities to covered retailers, however, already obtain this production step information needed either to pre-label retail case-ready products with production step information or to provide that information to their retail customers. In the latter scenario, the retailer would then complete the labeling of the production steps to provide notification to consumers.

Under current mandatory COOL requirements, packers and processors must inform their retail customers as to the country of origin of the meat cuts that they supply. In turn, that means that packers and processors must obtain the country of origin information from their supply chain. Thus, the information on production steps required by this proposal is already available due to the current mandatory COOL requirements. The additional costs attributable to the proposed

amendments would be the costs associated with transferring production step information to the product label.

For animals exclusively born, raised, and slaughtered in the United States, current labeling requirements would be augmented from, for example, "Product of the U.S." to "Born, Raised and Slaughtered in the U.S." In this example, the required statement increases from 19 to 40 characters and spaces. For animals born in another country and raised and slaughtered in the United States, current labeling requirements would be augmented from, for example, "Product of U.S. and Country X" to "Born in Country X, Raised and Slaughtered in the U.S." Finally, for an animal imported for immediate slaughter, current labeling requirements would be augmented from, for example, "Product of Country X and the U.S." to "Born and Raised in Country X, Slaughtered in the U.S." In these examples, the required statement increases by a net of 20 characters and spaces.

In addition, commingling currently allowed under the current mandatory COOL regulations would no longer be available under the proposed amendments. For example, the current regulations allow muscle cut covered commodities derived from animals born, raised, and slaughtered in the United States that are commingled during a production day with muscle cut covered commodities derived from animals born in one or more other

countries to be designated as, for example, "Product of the United States, Country X, and Country Y" (§65.300(e)(2)). That type of commingling would not be allowed under the proposed amendments, as the labels must be specific as to where the animal was born, raised, and slaughtered.

The Agency's experience with the current program suggests that the majority of muscle cut covered commodities are not produced and labeled using the labeling scheme afforded by commingling. The Agency invites comment and data regarding the extent to which the flexibility afforded by commingling on a production day is used to designate the country of origin under the current COOL program and the potential costs, such as labor and capital costs, which may result from the loss of such flexibility.

Given that the information needed to label production steps is already available and that most packers already segregate animals of differing countries of origin in the slaughter and processing of those animals,¹ the most widespread cost of implementing the proposed amendments is expected to be related to label change; this cost would be incurred partially at the

¹ For a discussion of various studies regarding the extent of segregation and commingling, see Appellate Body Reports, US - Certain Country of Origin Labelling (COOL) Requirements, WT/DS384/R, WT/DS386/R, paras. 295-310 (adopted July 23, 2012); Panel Reports, United States - Certain Country of Origin Labelling (COOL) Requirements, paras. 7.365, 7.403 (adopted July 23, 2012).

packing or processing facility and partially at the retail level.

In the FRIA published in the earlier COOL rulemaking (74 FR 2681), first-year incremental implementation costs for mandatory COOL were estimated at \$1,755 million for the beef, pork, lamb and goat, and chicken industries. Of that total, intermediary suppliers and retailers were estimated to incur costs of \$618 million and \$716 million respectively, for a total of \$1,334 million. Applying a Consumer Price Index deflator of 1.07 to convert to 2012 dollar values, first-year implementation costs for startup of mandatory COOL was estimated at \$661 million for intermediaries, \$766 million for retailers, and \$1,427 million for both industry segments. AMS believes that packer and processor intermediary suppliers and retailers would be able to add the proposed specific production step information to currently required COOL designations at considerably lower cost than required for initial implementation of the current COOL regulations.

In a 2010 survey of retail meat cases, 31 percent of beef, 58 percent of pork, 60 percent of lamb, and 94 percent of chicken packages were case ready packages.² For retailers,

² "A Snapshot of Today's Retail Meat Case: 2010 National Meat Case Study Executive Summary."
<http://www.beefretail.org/CMDocs/BeefRetail/research/2010NationalMeatCaseStudy.pdf>

products pre-labeled with production step locations would require no additional costs, as suppliers would add the production step information. Retailers offering case ready packages that do not include the production step information required under this proposed rule would need to communicate that information to consumers by some other means, such as placards or stickers. The Agency requests comment and data on the means retailers would utilize to communicate the production step information required by this proposed rule.

The estimated number of firms that would need to augment labels for muscle cut covered commodities is 2,808 livestock processing and slaughtering firms, 38 chicken processing firms, and 4,335 retailers (Table 1). This totals 7,181 firms that would need to augment the mandatory COOL information presented on labels for muscle cut covered commodities.

Cost estimates provided in a March 2011, Food and Drug Administration (FDA) report³ represent one possible approach for estimating the cost of including the additional production step information to currently required COOL labels for muscle cut covered commodities. There are limitations, however, to the applicability of the FDA label cost model to the task faced by

³ Model to Estimate Costs of Using Labeling as a Risk Reduction Strategy for Consumer Products Regulated by the Food and Drug Administration, FDA, March 2011 (Contract No. GS-10F-0097L, Task Order 5).

retailers in informing consumers of the production step locations as proposed herein.

Importantly, the FDA model was developed for all products subject to FDA regulation, which includes not only food, but cosmetics, dietary supplements, over-the-counter medications, pet foods, retail medical devices, and tobacco products and accessories. Most of the products covered by these categories are sold in fixed-volume or fixed-quantity packages that are labeled by the manufacturer, processor, or distributor, with no additional labeling added by the retailer.

However, this proposed rule covers muscle cut covered commodities, which notably fall outside of FDA's jurisdiction (and are not included within the model). As noted previously, unlike the FDA covered commodities, a significant percentage of muscle cut covered commodities are sold in random-weight packages, with the final weight and price label applied by the retailer. Typically, retailers use a label printing scale with a thermal dot printer to apply the unit price, weight, total price, and other information such as the product name, sell by date, and so forth on pressure-sensitive paper labels that are applied to packages prior to sale. This important difference between the products covered by this rule and the products contemplated by FDA in creating its model indicates to the AMS that it would be inappropriate to rigidly adhere to the model

for purposes of this analysis, as such an application of the model will overestimate the label change costs of this rule.

Nevertheless, despite these important limitations, the Agency does consider that the FDA model, with some qualifications can contribute to an assessment of the potential impacts of the proposed requirements. In the context of the FDA model, the proposed labeling change is assumed to be a minor change in which only one color is affected and the label does not need to be redesigned. Examples of a minor label change include the addition of a toll-free number, or more pertinent in this case, minimal changes to a claim on the back or side of a package affecting one color.

Based on 2009 data, the Food Safety and Inspection Service (FSIS) estimated there were approximately 121,350 raw meat and poultry unique labels submitted by official establishments and approved by the Agency (76 FR 44862). This number would represent an upper bound on the number of unique labels that would be affected by this proposed rule, as there are raw meat and poultry products that are exempt from COOL requirements, (such as a teriyaki flavored pork loin and other processed food items as defined by §65.220) or that are not affected by this proposed rule (such as turkey), and that are not sold at retail establishments (such as products sold to hotels, restaurants, and institutional customers). The Agency welcomes data that

would account for such products and thus allow for refinement of the estimate of the number of labels affected by the proposed rule.

Label changes in the FDA model fall on a spectrum from being uncoordinated, in which the label change does not correspond to a planned change, or coordinated, in which the label change corresponds with a planned change. The model predicts that coordinated label changes incur lower costs compared to uncoordinated changes. The Agency recognizes that costs estimates under the FDA model are greatly affected by the time over which required labeling changes are phased in. In the case of food products under the FDA model, any compliance period of less than 12 months is assumed to be an uncoordinated change, with 100 percent coordinated changes assumed to require at least 24 months for branded foods and 42 months for private label foods. The model predicts that coordinated label changes incur significantly lower costs compared to uncoordinated changes.

For the reasons explained above, the Agency does not believe that the rigid application of the FDA model will accurately predict the costs of this rule. In particular, the Agency does not consider that the distinction between coordinated and uncoordinated label changes as applied in the FDA label cost model is predictive of the costs of this rule. Rather, the Agency preliminarily estimates that label changes

proposed in this rule will create costs that correspond to a coordinated change, even if the Agency ultimately decides to require a phase in that is considerably shorter than 12 months, which the FDA model assumes is a 100 percent uncoordinated label change.

Under the FDA model, one-time costs for a coordinated label change are assumed to involve only administrative labor costs and recordkeeping. However, as previously discussed, no additional recordkeeping costs are anticipated from this proposed rule. The midpoint estimate of administrative labor cost for a coordinated label change is \$270, with a range of \$140-\$390. For an uncoordinated label change, the model includes administrative labor costs, non-administrative labor costs, materials costs that vary with the type of material and printing method, and recordkeeping costs. Again, no additional recordkeeping costs are anticipated from this proposed rule, and therefore the Agency considers that the model's predictions regarding uncoordinated label changes would significantly overstate the costs of the label change proposed here. As a point of reference, depending on the printing method, low estimates for coordinated change under the FDA model range from \$1,990 to \$2,940; midpoint estimates range from \$3,690 to \$4,980; and high estimates range from \$6,500 to \$7,890.

There are additional distinctions between the FDA model and the COOL regime to support the conclusion that the model's assumptions regarding coordinated versus uncoordinated label changes have limited applicability in this situation. As previously mentioned, COOL information already is made available to consumers under current regulations, and that information can be provided through a variety of means, including placards, signs, labels, stickers, or other formats. Thus, the Agency believes that the label changes contemplated in this proposed rule could be phased in with similar costs as predicted for a coordinated label change under the model. For instance, placards could be used to convey the augmented production step information pending synchronization with a coordinated label change cycle. Also, many, if not most, of the muscle cut covered commodities are sold as random-weight items with price, weight, and other information (including COOL information) printed for each individual package, thus allowing production step information to be provided in a similar manner. Assuming the upper bound estimate of 121,350 unique labels, the estimated midpoint cost of the proposed rule for a label change is \$32,764,500 with a range of \$16,989,000 to \$47,326,500 million.

Note that the number of unique labels affected by this proposed rule is expected to be lower than the upper-bound estimate of 121,350, thus lowering the total estimated costs

commensurately. Conversely, coordinating the proposed label changes with the current COOL requirements may involve additional costs that have not been included, which would result in higher overall costs than are estimated here.

Furthermore, compared to the current COOL program, the changes contemplated by the proposed amendments may involve ongoing activities beyond label redesign. For example, without the commingling possible under the current program, there may be a more frequent need to switch labels at processing plants that may currently commingle meat or enter different information into a label machine at a retail store when production step information changes. A given lot of carcasses or a box of meat from a production day may be of one origin, while the next lot or box may be of another origin. As previously explained, under some scenarios, under current COOL regulations, the same COOL designation can be applied to the entire day's production. Under the proposed amendments, however, the COOL designation would need to reflect the appropriate birth and raising country of origin information along with the United States location of slaughtering for individual muscle cuts of meat.

The Agency invites public comment and associated quantitative data that would improve the Agency's estimate of the cost of the changes in the labeling and commingling requirements being proposed in this rulemaking, including any

additional costs that have not been included in the estimates discussed above. The Agency also invites public comment on how the length of time for compliance will affect the cost of the changes being proposed in this rule.

Table 1—Estimated Number of Affected Entities, Share of Firms by Size, and Labeling Cost of Rule Revision*						
NAICS CODE	NAICS DESCRIPTION	ENTERPRISE SIZE CRITERIA	NUMBER OF FIRMS	NUMBER OF ESTABLISHMENTS	SHARE OF FIRMS BY SIZE	ESTIMATED COST OF RULE REVISION
311611	Animal (except Poultry) Slaughtering	<500 Employees	1,504	1,518	97.6%	\$ 1,491,344
		500+ Employees	37	115	2.4%	\$ 112,981
		Total	1,541	1,633		\$ 1,604,325
311612	Meat Processed from Carcasses	<500 Employees	1,203	1,232	94.9%	\$ 1,201,366
		500+ Employees	64	173	5.1%	\$ 169,962
		Total	1,267	1,405		\$ 1,380,328
311615	Chicken Processing	<500 Employees	36	N/A	94.7%	N/A
		500+ Employees	2	N/A	5.3%	N/A
		Total	38	156		\$ 153,261
445110	Supermarkets and Other Grocery (except Convenience) Stores, Sales >\$5,000,000	<\$50,000,000 Sales	4,106	6,050	95.0%	\$ 5,943,762
		\$50,000,000+ Sales	217	19,846	5.0%	\$ 19,497,504
		Total	4,323	25,896		\$ 25,441,266
452910	Warehouse Clubs and Supercenters	<\$50,000,000 Sales	0	0		\$ -
		\$50,000,000+ Sales	12	4,260	100.0%	\$ 4,185,194
		Total	12	4,260		\$ 4,185,195
GRAND TOTAL			7,181	33,350		\$32,764,500
*We assume that each establishment, regardless of size or industry, incurs the average estimated label revision cost per establishment = \$982.44. Numbers may not sum due to rounding.						
SOURCE: 2007 County Business Patterns and 2007 Economic Census.						

Initial Regulatory Flexibility Analysis

This rule has been reviewed under the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 et seq.). The purpose of the RFA is to consider the economic impact of a rule on small businesses and evaluate alternatives that would accomplish the objectives of the rule without unduly burdening small entities or erecting barriers that would restrict their ability to compete in the marketplace. The Agency believes that this rule will have a relatively small economic impact on a substantial number of small entities. As such, the Agency has prepared the following initial regulatory flexibility analysis of the rule's likely economic impact on small businesses pursuant to section 603 of the RFA.

As mentioned in the summary above, this rulemaking was contemplated after the Agency reviewed the overall regulatory program in light of the WTO's finding that the current mandatory COOL measure is inconsistent with the United States' WTO obligations. The objective of this proposed rulemaking is to amend current mandatory COOL requirements to provide consumers with information on the country in which productions steps occurred for muscle cut covered commodities, thus fulfilling the program's objective of providing consumers with information on origin. The legal basis for the mandatory COOL regulations is

Subtitle D of the Agricultural Marketing Act of 1946 (Act) (7 U.S.C. 1638 et seq.).

Under preexisting Federal laws and regulations, origin designations for muscle cut covered commodities need not specify the production steps of birth, raising, and slaughter of the animals from which the cuts are derived. Thus, the Agency has not identified any Federal rules that would duplicate or overlap with this rule.

We do not anticipate that additional recordkeeping will be required or that new systems will need to be developed to transfer information from one level of the production and marketing channel to the next. However, information available to consumers at retail will need to be augmented to include information on the location in which the three major production steps occurred. Therefore, the companies most likely to be affected are packers and processors that produce case-ready products, and retailers.

There are two measures used by the Small Business Administration (SBA) to identify businesses as small: sales receipts or number of employees.⁴ In terms of sales, SBA classifies as small those grocery stores with less than \$30

⁴ Small Business Administration.
[http://www.sba.gov/sites/default/files/files/Size_Standards_Table\(1\).pdf](http://www.sba.gov/sites/default/files/files/Size_Standards_Table(1).pdf)

million in annual sales (13 CFR 121.201). Warehouse clubs and superstores with less than \$30 million in annual sales are also defined as small. SBA defines as small those manufacturing firms with less than 500 employees and wholesalers with less than 100 employees.

While there are many potential retail outlets for the covered commodities, food stores, warehouse clubs, and superstores are the primary retail outlets for food consumed at home. In fact, food stores, warehouse clubs, and superstores account for 75.6 percent of all food consumed at home.⁵

Therefore, the number of these stores provides an indicator of the number of entities potentially affected by this rule. The 2007 Economic Census⁶ shows there were 4,335 supermarkets and grocery stores (not including convenience stores), warehouse clubs, and superstore firms operated for the entire year with annual sales exceeding \$5,000,000 (Table 1). We assume that stores with overall sales above this threshold would be most likely to be subject to the PACA and therefore subject to mandatory COOL and the proposed amendments. We recognize that there may be retail firms, particularly smaller retail firms,

⁵ ERS, USDA. Food CPI, Prices and Expenditures: Sales of Food at Home by Type of Outlet.
<http://www.ers.usda.gov/Briefing/CPIFoodAndExpenditures/Data/table16.htm>

⁶U.S. Census Bureau. 2007 Economic Census. Retail Trade Subject Series. Establishment and Firm Size. EC0744SSSZ4 and EC0744SSSZ1. Issued January 2013.

subject to PACA but that do not actually hold a PACA license. Therefore, a lower annual sales threshold may be appropriate for estimating the number of retailers subject to PACA. However, the \$5,000,000 threshold provides estimated firm and establishment numbers that are generally consistent with the PACA database listing licensed retailers.

The 2007 Economic Census data provide information on the number of food store firms by sales categories. Of the 4,335 food store, warehouse club, and superstore firms with annual sales of at least \$5,000,000, an estimated 4,106 firms had annual sales of less than \$50,000,000, which is higher than the threshold for the SBA definition of a small firm. The Economic Census data do not provide a breakout at the \$30,000,000 SBA threshold, which means that the estimated number of small businesses likely is an overestimate.

We estimate that 33,350 establishments owned by 7,181 firms will be either directly or indirectly affected by this rule (Table 1). Of these establishments/firms, we estimate that 6,849 qualify as small businesses. The mid-point total direct incremental costs are estimated for the proposed rule at approximately \$32.8 million. The direct incremental costs of the proposed rule are the result of revisions in labeling of muscle cut covered commodities. Of the total labeling costs of \$32.8

million, \$8.6 million is estimated to be costs borne by small businesses.

Small retailers' portion of these costs is estimated at \$5.9 million. Mid-point estimated costs are \$982 per retail establishment.

Any manufacturer that supplies retailers or wholesalers with a covered commodity will be required to provide revised country of origin information to retailers so that the information can be accurately supplied to consumers. Of the manufacturers potentially affected by the rule, SBA defines those having less than 500 employees as small.

The 2007 Economic Census⁷ provides information on manufacturers by employment size. For livestock processing and slaughtering there is a total of 2,808 firms (Table 1). Of these, 2,707 firms have less than 500 employees. This suggests that 96 percent of livestock processing and slaughtering operations would be considered as small firms using the SBA definition. For chicken processing there are a total of 38 firms, only two of which are classified as small. Thus, only 5 percent of the chicken processors are small businesses.

⁷ U.S. Census Bureau. 2007 Economic Census. Historical Data Tabulations by Enterprise Size. 2007 Annual Tabulations: U.S., All Industries. <http://www.census.gov/econ/susb/data/susb2007.html>

Small packer and processor labeling costs under the proposed rule are estimated at \$2.7 million. As with retailers, labeling costs are estimated at \$982 per establishment.

The Agency seeks comment on the accuracy of these estimates and the impacts on small businesses that may not be captured using the label cost model discussed above.

Alternatives considered: Section 603 of the RFA requires the Agency to describe the steps taken to minimize any significant economic impact on small entities including a discussion of alternatives considered. The law explicitly identifies those retailers required to provide their customers with country of origin information for covered commodities (namely, retailers subject to PACA). Thus, the proposed amendments are consistent with the requirements of the Act in terms of who is subject to the proposed rule.

The proposed change in the definition of a retailer is not expected to have a substantial effect on the number of retailers subject to COOL requirements. The PACA program continually monitors the retail industry for firms that may meet the threshold for PACA licensing and seeks to enforce compliance with those requirements. Thus, those retailers that are required to hold a PACA license should, in fact, be licensed separate and apart from any COOL program requirements.

The Agency considered other alternatives including taking no action or providing less information than is currently required under the COOL regulations. These alternatives would not achieve the purpose of this rulemaking.

As with the current mandatory COOL program, the proposed rule has no requirements for firms to report to USDA. Compliance audits will be conducted at firms' places of business. There are no recordkeeping requirements beyond those currently in place, and we believe that the information necessary to transmit production step information largely is already in place within the affected industries. As stated in the RFA of the COOL final rule, the current COOL requirements provide the maximum flexibility practicable to enable small entities to minimize the costs on their operations. This proposed rule in large measure retains these flexibilities. In addition, small packers, processors, and retailers are expected to produce and stock a smaller number of unique muscle cut covered commodities compared to large operations. Thus, labeling costs for small establishments likely will be lower than the estimated mid-point average of \$982 for all establishments.

Paperwork Reduction Act

Pursuant to the Paperwork Reduction Act (PRA) (44 U.S.C 3501-3520) the information collection provisions contained in

this rule were previously approved by OMB and assigned OMB Control Number 0581-0250. On December 4, 2012, AMS published a notice and request for comment seeking OMB approval to revise this information collection. The comment period closed on February 4, 2013. This proposed rule does not change these provisions.

Executive Order 12988

The contents of this rule were reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have a retroactive effect. States and local jurisdictions are preempted from creating or operating country of origin labeling programs for the commodities specified in the Act and these regulations. With regard to other Federal statutes, all labeling claims made in conjunction with this regulation must be consistent with other applicable Federal requirements. There are no administrative procedures that must be exhausted prior to any judicial challenge to the provisions of this rule.

Civil Rights Review

AMS considered the potential civil rights implications of this rule on minorities, women, or persons with disabilities to ensure that no person or group shall be discriminated against on the basis of race, color, national origin, gender, religion, age, disability, sexual orientation, marital or family status, political beliefs, parental status, or protected genetic

information. This review included persons that are employees of the entities that are subject to these regulations. This proposed rule does not require affected entities to relocate or alter their operations in ways that could adversely affect such persons or groups. Further, this rule will not deny any persons or groups the benefits of the program or subject any persons or groups to discrimination.

Executive Order 13132

This rule has been reviewed under Executive Order 13132, Federalism. This Order directs agencies to construe, in regulations and otherwise, a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence to conclude that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute. This program is required by the 2002 Farm Bill, as amended by the 2008 Farm Bill.

In the January 15, 2009, final rule, the Federalism analysis stated that to the extent that State country of origin labeling programs encompass commodities that are not governed by the COOL program, the States may continue to operate them. It also contained a preemption for those State country of origin labeling programs that encompass commodities that are governed

by the COOL program. This proposed rule does not change the preemption. With regard to consultation with States, as directed by the Executive Order 13132, AMS previously consulted with the States that have country of origin labeling programs. AMS has cooperative agreements with all 50 States to assist in the enforcement of the COOL program and has communications with the States on a regular basis.

Because the United States wants to provide more specific information to the consumer at the earliest possible date, and consequently to bring COOL into compliance with the WTO ruling by May 23, 2013, the Agency has determined that a 30-day comment period is appropriate.

For the reasons set forth in the preamble, 7 CFR part 60 is proposed to be amended as follows:

PART 60--COUNTRY OF ORIGIN LABELING FOR FISH AND SHELLFISH

1. The authority citation for part 60 continues to read as follows:

Authority: 7 U.S.C. 1621 et seq.

2. Section 60.124 is revised to read as follows:

§60.124 Retailer.

Retailer means any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a(b)).

For the reasons set forth in the preamble, 7 CFR part 65 is proposed to be amended as follows:

PART 65--COUNTRY OF ORIGIN LABELING OF BEEF, PORK, LAMB, CHICKEN, GOAT MEAT, PERISHABLE AGRICULTURAL COMMODITIES, MACADAMIA NUTS, PECANS, PEANUTS, AND GINSENG

1. The authority citation for part 65 continues to read as follows:

Authority: 7 U.S.C. 1621 et seq.

2. Section §65.240 is revised to read as follows:

§65.240 Retailer.

Retailer means any person subject to be licensed as a retailer under the Perishable Agricultural Commodities Act of 1930 (7 U.S.C. 499a(b)).

3. Section 65.300 paragraphs (d), (e), and (f) are revised to read as follows:

(d) Labeling Covered Commodities of United States Origin.

A covered commodity may bear a declaration that identifies the United States as the sole country of origin at retail only if it meets the definition of United States country of origin as defined in §65.260. The United States country of origin designation for muscle cut covered commodities shall include all of the production steps (i.e., "Born, Raised, and Slaughtered in the United States").

(e) Labeling Muscle Cut Covered Commodities of Multiple Countries of Origin from Animals Slaughtered in the United States.

If an animal was born and/or raised in Country X and/or (as applicable) Country Y, and slaughtered in the United States, the resulting muscle cut covered commodities shall be labeled to specifically identify the production steps occurring in each country (e.g., "Born and Raised in Country X, Slaughtered in the United States"). If an animal is raised in the United States as well as another country (or multiple countries), the raising occurring in the other country (or countries) may be omitted from the origin designation except if the animal was imported for immediate slaughter as defined in §65.180 or where by doing so the muscle cut covered commodity would be designated as having a United States country of origin (e.g., "Born in Country X, Raised and Slaughtered in the United States" in lieu of "Born and Raised in Country X, Raised in Country Y, Raised and Slaughtered in the United States").

(f) Labeling Imported Covered Commodities.

(1) Perishable agricultural commodities, peanuts, pecans, ginseng, macadamia nuts and ground meat covered commodities that have been produced in another country shall retain their origin, as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale.

(2) Muscle cut covered commodities derived from an animal that was slaughtered in another country shall retain their origin, as declared to U.S. Customs and Border Protection at the time the product entered the United States, through retail sale (e.g., "Product of Country X"), including muscle cut covered commodities derived from an animal that was born and/or raised in the United States and slaughtered in another country. In addition, the origin declaration may include more specific location information related to production steps (i.e., born, raised, and slaughtered) provided records to substantiate the claims are maintained and the claim is consistent with other applicable Federal legal requirements.

Date: March 7, 2013

Robert Epstein, Ph.D.
Acting Administrator

Billing Code: 3410-02P

[FR Doc. 2013-05576 Filed 03/11/2013 at 8:45 am; Publication

Date: 03/12/2013]